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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/575,830 | KUTUSHOV, MIKHAIL VLADIMIROVICH | |
| Examiner | Art Unit | | |
| Brian Walck | 1793 | | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 February 2009.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 6-16 and 20-30 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-5 and 17-19 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Status of Claims

1. Claims 1-30 are pending where claims 1-4, 6-17, and 20-30 have been amended.

Election/Restrictions

2. Newly amended claims 6-16 and 20-30 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the ferreed sorbent of claims 1-2 can be made by a materially different process (such as by taking small nickel flakes as disclosed by US 3419901 and dipping them in paint or any other coating material) than the process of claims 6-16 and 20-30.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 6-16 and 20-30 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. **Claims 1-5 and 17-19 are rejected under 35 U.S.C. 103(a) as obvious over Russian Patent No. 2178313 to Kutushov.**

Page 1, paragraph [0006] of the specification of the instant application states that Russian Patent No. 2178313 to Kutushov discloses;

"[a] ferreed sorbent (FS), with the atomic centre or core as grading fraction with particle size of (0.1-1000) mc, made of iron, iron oxides, nickel, or iron-nickel alloy, and coated with a single or double layer coat of carbon, aluminum oxide, silicon dioxide, zirconium dioxide, dextrane, e.g. sephadex, gelatin, albumin, polysaccharide, e.g. amyłum, or ion-exchange resins, e.g. cations or anions, where the coat upper layer is either conjugated with antibodies, or modified by pharmaceutical composition, e.g. antibiotics or phthalhydrazide salines, e.g. 5-amino-2,3-dihydro-1,4-dione salines or else fermented e.g. with urease."

Regarding claim 1, RU 2178313 to Kutushov discloses a ferreed sorbent having a ferromagnetic core, with one of a single layer coat or a double layer coat, comprising: the core made in a form of a particle (which in the broadest sense of the term would be

a flake) with a particle size of 0.1-1000 μm , which overlaps the instantly claimed limitation of dimensions in a plane of 500-5000 μm and with a thickness of 0.1-1000 μm in the region of 500-1000 μm and when the plane dimension is negligibly greater than the thickness. In the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a *prima facie* case of obviousness exists (see MPEP 2144.05 [R-5]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected values for particle size that lie within the instantly claimed ranges because RU 2178313 to Kutushov discloses the same utility throughout the disclosed ranges. Although RU 2178313 to Kutushov does not explicitly disclose that the plane dimension of the flake is greater than the thickness, the particles of RU 2178313 to Kutushov would inherently possess a plane dimension at least infinitesimally greater than the thickness, unless somehow the particles of RU 2178313 to Kutushov are *perfectly* spherical (which is essentially impossible).

The further limitations of instant claims 2-5 and 17-19 are found in RU 2178313 to Kutushov’s disclosure of:

"[a] ferreed sorbent (FS), with the atomic centre or core... made of iron, iron oxides, nickel, or iron-nickel alloy, and coated with a single or double layer coat of carbon, aluminum oxide, silicon dioxide, zirconium dioxide, dextrane, e.g. sephadex, gelatin, albumin, polysaccharide, e.g. amylose, or ion-exchange resins, e.g. cations or anions, where the coat upper layer is either conjugated with antibodies, or modified by pharmaceutical

composition, e.g. antibiotics or phthalhydrazide salines, e.g. 5-amino-2,3-dihydro-1,4-dione salines or else fermented e.g. with urease"

6. Claims 1-30 are rejected under 35 U.S.C. 102(b) as being obvious over US Patent 5980479 to Kutushov.

The specifications of US 5980479 to Kutushov, column 5 line 42 to column 6 line 22, discloses:

"[A] biocompatible magneto-conductive material is in the form of paramagnetic or ferromagnetic particles... The particles are formed of one of the following materials: iron in its reduced form, so-called 'ferrum reductum'; iron oxide; carbon coated iron; dextran coated iron, silicone coated iron, aluminum coated iron... The particles of either kind are, then, specifically processed so as to have swelled, activated surfaces for possessing the following properties: high adsorption capability..."

...

Moreover, the particle is of substantially small size about 0.01 μ m to 1 mm...

...

Optionally, the particles may be further coated by a protective coating formed of either protein of any known kind, particularly a food protein, or the patient's blood, so-called 'auto-blood'. Alternatively, or additionally, the particles may be coated by a selective coating, for example antibody, depending on a preselected pathogenic agent to be removed from the

biological fluid. Moreover, the paramagnetic particle either coated or not may be further modified by antibiotics or similar medical compounds."

Regarding claim 1, in US 5980479 to Kutushov discloses a ferreed sorbent having a ferromagnetic core, with one of a single layer coat or a double layer coat, comprising: the core made in a form of a particle (which in the broadest sense of the term would be a flake) with a particle size of 0.1-1000 μm , which overlaps the instantly claimed limitation of dimensions in a plane of 500-5000 μm and with a thickness of 0.1-1000 μm in the region of 500-1000 μm and when the plane dimension is negligibly greater than the thickness. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists (see MPEP 2144.05 [R-5]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected values for particle size that lie within the instantly claimed ranges because in US 5980479 to Kutushov discloses the same utility throughout the disclosed ranges. Although in US 5980479 to Kutushov does not explicitly disclose that the plane dimension of the flake is greater than the thickness, the particles of in US 5980479 to Kutushov would inherently possess a plane dimension at least infinitesimally greater than the thickness, unless somehow the particles of in US 5980479 to Kutushov are *perfectly* spherical (which is essentially impossible).

The further limitations of instant claims 2-3, 17 are found in US 5980479 to Kutushov's disclosure of

“The particles are formed of one of the following materials: iron in its reduced form, so-called ‘ferrum reductum’; iron oxide; carbon coated iron; dextran coated iron, silicone coated iron, aluminum coated iron”

With respect to instant claims 4 and 18, US 5980479 to Kutushov discloses “the particles may be further coated by a protective coating formed of... protein of any known kind, particularly a food protein or the patient’s blood.” Since albumin is a protein found in human blood, this disclosure reads on the outer layer coat of albumin limitation of instant claims 4 and 18.

With respect to instant claims 5 and 19, US 5980479 to Kutushov discloses “the paramagnetic particle either coated or not may be further modified by antibiotics or similar medical compounds.” This reads on the conjugation with antibiotics limitation of instant claims 5 and 19.

Response to Arguments

7. Applicant’s arguments, see page 18 first paragraph, filed 2/17/2009, with respect to the 35 USC 112 rejection have been fully considered and are persuasive. In new amendments to claim 1, applicant has clarified what applicant considers a flake. The 35 USC 112 rejection of claims 1-30 has been withdrawn.

8. Applicant’s arguments, see page 18 fourth paragraph, filed 2/17/2009, with respect to the 35 USC 102(b) rejection of claims 1-2 as anticipated by US 3419901 have been fully considered and are persuasive. In new amendments to claim 1, applicant has amended claim 1 such that the ferreed sorbent must have one or two

coats, which US 3419901 does not explicitly teach. The 35 USC 102(b) rejection of claims 1-2 as anticipated by US 3419901 of claims 1-2 has been withdrawn.

9. Applicant's arguments with respect to the 35 USC 102(b) rejection of claims 1-30 as anticipated by RU 2178313 as well as applicant's arguments with respect to the 35 USC 102(b) rejection of claims 1-30 as anticipated by US 5,980,479 have been considered but are moot in view of the new ground(s) of rejection. See above for new reasoning necessitated by the amendments to the claims.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Walck whose telephone number is (571)270-5905. The examiner can normally be reached on Monday-Friday 9 AM-6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Roy King can be reached on (571)272-1244. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Roy King/
Supervisory Patent Examiner, Art
Unit 1793

/Brian Walck/
Examiner, Art Unit 1793